

REMARKS

Claims 1-13 and 17 are canceled due to restrictions imposed by the Examiner and required to be withdrawn from consideration. Independent claim 13 has been canceled and claim 14 (which depended from claim 13) is amended to incorporate the limitations of independent claim 13 and that that backing construction outer layer has a breathable material. Support for the amendment can be found in the specification, e.g., in the original claims and in Fig. 2. Claim 15 is amended to depend on claim 14 instead of claim 13 due to cancellation of claim 13. New claims 18-30 are added. Support for the newly added claims can be found throughout the disclosure of the application, for example, in the drawings, the original claims, and in the specification. For example, paragraphs [00032] to [00037] contain description related to the secondary drug-containing reservoir. No new matter is added in the amendment or the new claims. Thus, claims 14-16, and 18-30 are pending.

Telephone Interview

Applicant notes with appreciation the courtesy extended to Applicant's attorney, Philip Yip, in the telephone interview of January 5, 2006. During the telephone interview, the various restriction requirement categories were discussed. Applicant's attorney pointed out with such restrictions even closely related embodiments are restricted and that requiring insertion of such details in the claims would render the claims exceedingly narrow. Further, the reason why antagonist can have utility without necessarily going through the base layer of the backing was discussed. Applicant's attorney agreed to explain in the written response why there is utility with the antagonist not necessarily going through the base layer of the backing.

Election/Restrictions

The Examiner imposed restriction requirements on four categories: I. Outer layer; II. Tie layer structure; III. Reservoir; and IV. Release controlling means.

As the undersigned attorney had mentioned in the telephone interview, Applicant is interested in prosecuting the invention related to currently presented independent claim 14. Applicant hopes that dependent claims depending on claim 14 will also be examined and respectfully request help from the Examiner to select the right categories to achieve that goal.

According the MPEP 803, the examiner can impose restriction if the claimed inventions are independent and distinct and further, the examiner must examine the claim inventions together if the search and the examination can be done without serious burden. Further, MPEP 806.05(j) points out that restriction is proper between related product inventions or between related process invention only where there is two way distinction. Thus, Applicant respectfully asks that the Examiner examine independent claim 14 and claims 15-16 and 18-30 (all of which dependent on claim 14 except claim 30) because they are all product claims and are closely related to claim 14.

- 1) Regarding species election requirement 1, Applicant traverses the Examiner's requiring Applicant to select a single material from the list of materials in Claim 2 and claim 3. The breathable material in claim 2 and claim 3 can be any of the listed materials of claim 3 (such as porous, microporous, microfibrillar, ... etc.) and these breathable materials are closely related. Applicant should be allowed to prosecute the application based on breathable material without being forced to narrowly limit to, let us say for example, rayon. If that is all Applicant is permitted to do, when Applicant gets an issued claim, someone can easily go around the claim by picking another polymer rather than rayon. To protect the inventions of the present application, if Applicant is forced to do what the Examiner requires, Applicant will have to file dozens, may be hundreds, of applications to covers the various permutations and combinations of the features in the four categories of election the Examiner requires Applicant to choose from. Nevertheless, to not further delay prosecution, Applicant respectfully requests the Examiner to examine the claims related to currently amended claim 14, which are based on microporous layer or microfibrillar layer.

2) Regarding Species Category II on multilaminate tie layer, Applicant disagrees with the Examiner. Contrary to what the Examiner says, claims 1, 7, 8, and 12 are not merely directed to an embodiment in which the tie layer is a single layer structure as shown in Figure 1. In claims 1, 7, 8, 12, Applicant uses "comprising", which means that there may or may not be additional features. Further there is nothing to preclude the tie layer in these claims to have multiple layers (such as what is similar to that shown in Figure 2). Further, Applicant traverses the Examiner's assertion that just because claims 1, 7, 8, 12 are independent claims they are independent and distinct and therefore claims 1-12 must be precluded by the election of multilaminate tie layer. By analogy, just because independent claim 1 says "a chair comprising a back and 4 legs" does not mean it is independent and distinct from claim 2 which says "a chair comprising a back and 5 legs" and claim 4 that says "a chair comprising a back and 6 legs". Claim 1 can mean a chair having 4 legs, 5 legs or 6 legs and claim 2 can mean a chair having 5 or 6 legs since "comprising" means "having at least". How can patent applicants be able afford filing and prosecuting applications for patents if they are required to separately file applications on every difference, even closed related differences?

Nevertheless, we are respectfully requesting the Examiner to examine presently presented independent claim 14 and claims related to it. Claim 14 addresses having multilaminate tie layer. But by multilaminate tie layer, we mean that the secondary drug reservoir can be one of the layers in the multilaminate tie layer (for example, as illustrated in exemplary Figure 2).

- 3) Regarding Category III, Applicant elects to prosecute amended claim 14 and related claims with a multilaminate tie layer and Applicant means that secondary drug reservoir layer can be one of the layers in the multilaminate tie layer, and that the drug can be a therapeutic drug (such as fentanyl) or an antagonist drug (such as an antagonist for fentanyl). Applicant respectfully traverses the Examiner's assertion that original claim 13 must be interpreted to be limited to having no drug reservoir. Original claim 13 comprises a multilaminate tie layer, but is silent on whether there is a drug reservoir. There is nothing to prevent it from including a drug reservoir as one of the layers in the multilaminate tie layer. Nevertheless, Applicant has amended dependent claim 14 (which includes a secondary drug-containing reservoir) to independent form and canceled original claim 13.
- 4) Regarding Category IV, Applicant was forced to elect between having a control membrane in the outer layer and in the base layer and was not given any other choice. Thus, to oblige, Applicant elected the outer layer regarding a control membrane. But it does not mean that there has to be a control membrane in the device, just that if we are going to prosecute a claim having control membrane, the election is on a membrane that is on the outer layer. Unless there is prior art reason, Applicant should not be forced to include every detail of variations from the description into his claim by restriction requirements and assertions that essential features have not been included in the claim.

It is noted that the Examiner did not explain what and how claimed inventions were independent and distinct in the four categories (for example, how microporous material is independent and distinct from breathable material or from microfibrillar material). Applicant respectfully hopes that the Examiner will accept Applicants election of the amended claims to move the prosecution forward.

35USC §112 first paragraph rejection

Claims 14-16 were rejected as based on a disclosure that is not enabling under 35USC §112 first paragraph. Applicant respectfully traverses the rejection. The Examiner asserted that the elected species "outer layer is an antagonist release rate controlling means and antagonist is not releasable through the base layer" is critical or essential to the practice of the invention, but not included in the claims is not enabled by the disclosure. The Examiner asserted that original claims 13 and 14 do not recite the limitations of the elected species and renders the scope of invention incomplete. As Applicant mentioned, Applicant elected on the outer layer as a control membrane only because Applicant was forced to choose between having a control membrane in the outer layer and the base layer and was given no other alternative. A claim is read in light of that essential features are included for the claimed invention to function. By analogy, for example, a claim on a chair comprising a back and legs does not necessarily need to specify that it has nails, or glues, unless there is prior art reasons to do so. (Nails or glue may or may not be used to make a chair since a good carpenter can make a chair without either.) Otherwise, by the Examiner's logic, just because there is description and drawing of various embodiments in the specification, the applicant would be forced to make election on legs, the back, nails, paints according to what was in the description and would have to state in a claim that the chair has, say 1 back, 4 legs, 20 nails, glue, paint, fabrics, staples, nylon threads and the material of each and more details, etc., rendering the claim too narrow to provide any protection to the inventor. Nevertheless, Applicant has included dependent claims regarding rate control on the outer layer. It is hoped that the Examiner will not force Applicant to include that feature in the main claim. Thus withdrawal of the rejection is respectfully requested.

Claims 14-16 were rejected as failing to comply with the written description requirement based on 35USC §112 first paragraph. Applicant respectfully traverses the rejection. The Examiner asserted that nowhere in the specification is there an embodiment of a multilaminate tie layer being incorporated with the limitation of "outer layer is an antagonist release rate controlling means and antagonist is not releasable through the base layer." Applicants respectfully directs the Examiner's attention to the last part of paragraph [00043], which states "the base layer 4 is impermeable to the antagonist ..."; to paragraph [00045], which states "when the secondary drug-containing reservoir is an antagonist-containing reservoir, the outer layer 2, 12, also functions as a drug release rate controlling means..."; and to paragraph [00034], which states that the antagonist can be made to come out when the secondary drug-containing reservoir is ingested or immersed in a solvent. Thus withdrawal of the rejection is respectfully requested.

35USC §101 rejection

Claims 14-16 were rejected under 35USC §112 first paragraph because the Examiner asserted that the disclosed invention is inoperative and therefore lacks utility. The Examiner asserted that "the outer layer is an antagonist release rate controlling means and antagonist is not releasable through the base layer" appears to render the invention inoperative because it prevents the drug from being delivered through the base layer to the skin. However, at least one utility of the antagonist is for deterring abuse, such as a person trying to ingest the drug material in the device or to solvent-extract the abusable drug from the device (as, for example, described in paragraph [00034] of the description. It is not necessary that the antagonist be used by way of diffusion through the base layer to the skin, since one utility is abuse deterrence and antagonist is released only during abuse of the device. Thus, withdrawal of the rejection is respectfully requested.

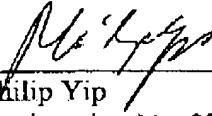
CONCLUSION

Applicant is eager to move the substantive examination forward and respectfully requests the Examiner's help to move past the restriction stage. Applicant submits the pending claims are novel and nonobvious over prior art and comply with the requirements of 35 USC §101 and §112. The examination and passage to allowance of the pending claims are respectfully requested. An early Notice of Allowance is therefore earnestly solicited. Applicant invites the Examiner to contact the undersigned at (650) 564-7054 to clarify any unresolved issues raised by this response.

The Commissioner is hereby authorized to charge any additional fees associated with this paper or during the pendency of this application, or credit any overpayment, to Deposit Account No. 10-0750.

Respectfully submitted,

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